

GAIL FARBER, Director

DEPARTMENT OF PUBLIC WORKS

"To Enrich Lives Through Effective and Caring Service"

COUNTY OF LOS ANGELES

900 SOUTH FREMONT AVENUE ALHAMBRA, CALIFORNIA 91803-1331 Telephone: (626) 458-5100 http://dpw.lacounty.gov

October 1, 2015

ADDRESS ALL CORRESPONDENCE TO: P.O. BOX 1460 ALHAMBRA, CALIFORNIA 91802-1460

IN REPLY PLEASE

REFER TO FILE:

EP-4 A4272F

TO:

Each Supervisor

FROM:

Gail Farber Maui Januar Director of Public Works

BOARD MOTION OF JUNE 2, 2015, ITEM 78-A MANAGING UNUSED AND EXPIRED MEDICATIONS AND SHARPS WASTE IN THE COUNTY OF LOS ANGELES

On June 2, 2015, the Board approved a motion instructing the Director of Public Works, in coordination with the Interim Chief Executive Officer, County Counsel, the Sheriff, the Directors of Health Services, Internal Services, Mental Health, Public Health, and the County Sanitation Districts to:

- 1. Investigate options for reducing improper use and disposal of unused/expired medications, increasing public awareness and education, and improving the current management system for unused/expired medications in the County;
- 2. Partner with the Pharmaceutical Industry to develop a public awareness campaign to educate residents on the importance of how to properly store and dispose of unused medication and the negative effects to the environment when medication enters the waste stream and waterways;
- 3. Actively support and pursue Extended Producer Responsibility (EPR) legislation and take-back programs for sharps and pharmaceuticals at the State level, consistent with the County's adopted Legislative Agenda and Roadmap to a Sustainable Waste Management Future;
- 4. Investigate the feasibility of adopting an ordinance similar to the pharmaceutical take-back ordinance adopted by the Counties of Alameda, San Mateo, San Francisco, and Santa Clara; and
- 5. Investigate the feasibility of utilizing the County's purchasing power to negotiate producer/pharmacy take-back programs.

Report back within 4 months with findings and recommendations for items 1 through 3 and report back in 30 days for items 4 and 5.

Each Supervisor October 1, 2015 Page 2

On July 2, 2015, a report was submitted to the Board in response to items 4 and 5 of the motion. The attached report is in response to items 1-3 of the June 2, 2015, Board motion, and also provides a brief status update regarding the activities undertaken by the Pharmaceutical Working Group in response to the August 11, 2015, Board motion.

The August 11, 2015, Board motion directed the Interim Chief Executive Officer, in collaboration with the County's Sustainability Council and the Pharmaceutical Working group to:

- Draft an ordinance which requires manufacturers and producers of prescription and nonprescription drugs and sharps to develop product stewardship take-back programs to collect and dispose of unused/unwanted pharmaceutical and sharps waste from County residents;
- 2. Initiate stakeholder engagement with the Pharmaceutical Industry and other stakeholders to solicit feedback on the ordinance; communicate the need to provide safe, convenient, and sustainably financed take-back options for consumers to properly dispose of pharmaceutical and sharps waste; and generate awareness about the collection program that will be created; and
- 3. Return to the Board within 6 months with the recommended Ordinance for consideration.

The Board amended the motion to have the stakeholder process occur first before the ordinance is drafted.

The recommended Ordinance, which will be submitted to the Board by February 11, 2016, will take into consideration the findings of the July 2, 2015, Board report "Managing Unused and Expired Medications and Sharps in the County of Los Angeles," feedback received from stakeholders and the public, as well as analyses of EPR ordinances and best practices developed and implemented by other jurisdictions.

If you have any questions regarding this report, please contact me or your staff may contact Shari Afshari at (626) 458-4008.

PH:il

P:\Secfinal\Pharma EPR Cover Memo 10_2_2015CEO_V3.doc

Attach.

cc: Chief Executive Office (Sachi A. Hamai, Rochelle Goff), County Counsel (Julia Weissman, Grace Chang, Lillian Russell), Executive Office, Department of Health Services, Internal Services Department, Department of Mental Health, Department of Public Health, Sheriff's Department, Sanitation Districts of Los Angeles County

MANAGING UNUSED AND EXPIRED MEDICATIONS AND SHARPS WASTE IN THE COUNTY OF LOS ANGELES

PART II

October 2, 2015

PREPARED BY:

Chief Executive Office
County Counsel
Department of Health Services
Internal Services Department
Department of Mental Health
Department of Public Health
Department of Public Works
Sheriff's Department
Sanitation Districts of Los Angeles County

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Introduction and Background

Board Motion

On June 2, 2015, the Board of Supervisors approved a motion directing the Director of Public Works, in coordination with the Interim Chief Executive Officer, County Counsel, the Sheriff, the Directors of Health Services, Internal Services, Mental Health, Public Health, and the County Sanitation Districts to:

- 1. Investigate options for reducing improper use and disposal of unused/expired medications, increasing public awareness and education, and improving the current management system for unused/expired medications in the County;
- 2. Partner with the Pharmaceutical Industry to develop a public awareness campaign to educate residents on the importance of how to properly store and dispose of unused medication and the negative effects to the environment when medication enters the waste stream and waterways;
- 3. Actively support and pursue Extended Producer Responsibility (EPR) legislation and take-back programs for sharps and pharmaceuticals at the State level, consistent with the County's adopted Legislative Agenda and Roadmap to a Sustainable Waste Management Future;
- 4. Investigate the feasibility of adopting an ordinance similar to the pharmaceutical take-back ordinance adopted by the Counties of Alameda, San Mateo, San Francisco, and Santa Clara; and
- 5. Investigate the feasibility of utilizing the County's purchasing power to negotiate producer/pharmacy take-back programs.

Report back within 4 months with findings and recommendations for items 1 through 3 and report back in 30 days for items 4 and 5.

The County Departments and Agency listed in the motion formed a Pharmaceutical Working Group (Working Group) to prepare this report, which is in response to items 1 through 3 above. In a report dated July 2, 2015 (see Appendix), the Working Group submitted a response to the Board regarding items 4 and 5 of the motion.

July 2, 2015, Board Report

The July 2, 2015, report to the Board of Supervisors, "Managing Unused and Expired Medications and Sharps in the County of Los Angeles," recognized that while pharmaceuticals play a critical role in treating diseases and saving lives, consumers of pharmaceutical products have limited options for disposal of excess or expired pharmaceutical supplies. In addition, the improper management of discarded sharps waste such as needles, syringes, and lancets can pose a health risk to residents, children, and certain classes of workers such as those that come in contact with waste at municipal solid waste material recovery facilities.

The disposal of pharmaceutical and sharps waste is a public health and safety issue and an environmental issue requiring safe, convenient, and sustainable disposal options for residents in the County of Los Angeles. The report recommended that the Board adopt a

pharmaceutical and sharps waste EPR Ordinance. It was further recommended that the Ordinance be similar to the ordinance adopted by Alameda County with the addition of over-the-counter pharmaceuticals as well as sharps waste. The report noted that while these other provisions have not been legally tested, the Working Group believes that the risks are outweighed by the public health and safety benefits and the environmental protection benefits.

August 11, 2015, Board Motion

In response to the July 2, 2015, report on August 11, 2015, the Board adopted a Motion introduced by Mayor Michael D. Antonovich and Supervisor Hilda L. Solis, and amended by Supervisor Don Knabe, which directed the Interim Chief Executive Officer, in conjunction with the County's Sustainability Council and the Pharmaceutical Working Group to:

- 1. Draft an Ordinance, which requires manufacturers and producers of prescription and nonprescription drugs and sharps to develop product stewardship take-back programs to collect and dispose of unused/unwanted pharmaceutical and sharps waste from County residents;
- 2. Initiate stakeholder engagement with the Pharmaceutical Industry and other stakeholders to solicit feedback on the Ordinance; communicate the need to provide safe, convenient, and sustainably financed take-back options for consumers to properly dispose of pharmaceutical and sharps waste; and generate awareness about the collection program that will be created; and
- 3. Return to the Board within 6 months with the recommended Ordinance for consideration.

The motion was amended to have the stakeholder process first before the Ordinance is drafted.

June 2, 2015, Board Motion Response

Item 1: Options for Reducing Improper Use and Disposal, Increasing Public Awareness and Education, and Improving the Current Management System for Pharmaceutical and Sharps Waste

The July 2, 2015, report (pages 4-6) included a discussion of existing options for managing pharmaceutical and sharps waste and focused on the broad consensus that take-back and mail-back programs provide for the environmentally safe collection and disposal of unwanted pharmaceutical and sharps waste. The report also noted California's prohibition on disposing of sharps waste in the trash or recycling bins. The report recommended the Board adopt an EPR Ordinance, which manufacturers and producers of pharmaceuticals and sharps develop and fund take-back programs providing collection services that are reasonably convenient and adequately meet the needs of the population being served. The California Department of Resources, Recycling and Recovery also recommended Product Stewardship as the preferred approach to managing pharmaceutical and sharps waste in their December 2010 report to the legislature, "Recommendations for Home-Generated Pharmaceutical Collection Programs in California." Options for increasing public awareness are further discussed in the next Section of this report.

Item 2: Partner with the Pharmaceutical Industry to Develop a Public Awareness Campaign to Educate Residents on the Importance of How to Properly Store and Dispose of Unused Medication and the Negative Effects to the Environment When Medication Enters the Waste Stream and Waterways

The Working Group recommends that a concerted effort to raise public awareness, in concert with the Pharmaceutical Industry and other stakeholders, be initiated following the adoption of the Ordinance by the Board, which will be submitted for Board consideration on February 11, 2016. This will reduce potential confusion between current, publicly financed programs and future programs that may be implemented.

The July 2, 2015, report recommended that the Ordinance contain provisions, which would allow manufacturers and producers or stewardship organizations the flexibility to design the Take-Back Program to meet performance goals established by the County. Among these performance goals would be an expectation that the Take-Back Program include a robust public awareness campaign. The campaign would need to educate residents on proper storage and disposal of unwanted pharmaceuticals and sharps waste, and the potential ramifications to health and safety of residents as well as the environment if these wastes are not properly disposed. Public awareness of the Take-Back Program will be essential for successful implementation of the program. The Working Group recommends that full implementation of a public awareness program take place after the Ordinance is adopted because it is important to have a safe, convenient and sustainable program in place to facilitate the collection of unwanted pharmaceutical and sharps waste prior to undertaking a significant public awareness campaign about improper disposal. This will also ensure that the public awareness program is funded, since it would be part of the EPR program.

Stakeholder Engagement:

In advance of preparing the draft Ordinance, as directed by the August 11, 2015, motion, the Working Group has initiated a robust stakeholder engagement process and Communications Plan. This plan is aimed at increasing awareness about the importance of proper disposal of pharmaceutical and sharps waste, and current efforts are focused on communicating about the development of a County ordinance with stakeholders and the public at large. The plan includes the following elements:

- **Pharmaceutical Take-Back Webpage** The County has developed a webpage dedicated to providing those interested a central hub for information related to the stakeholder process, including meeting details, and the overall purpose of this effort. The web address is http://publichealth.lacounty.gov/pharma.htm.
- Stakeholder and Public Awareness Meetings As part of the initial process, two meetings took place on September 28, 2015, at the Kenneth Hahn Hall of Administration to allow stakeholders to provide their initial feedback regarding the Board motion. The meeting included representatives from the Pharmaceutical Industry, pharmacies, hospitals, product stewardship advocates, environmental organizations, wastewater agencies, retailers, and sharps manufacturers, which serve as a Technical Advisory Group for the effort and who will be most directly affected by the implementation of the Ordinance. The afternoon meeting included

the general public and other stakeholders. Additional stakeholder and public meetings will take place during the development process of the Ordinance.

- **Webinar** The Working Group has set-up a webinar to increase the audience and facilitate easy access to the meetings live online.
- **Dedicated E-mail Address (EPR@lacounty.gov) to Obtain Feedback/Input** A specific electronic e-mail address has been set-up so that members of the public, stakeholders, and other organizations will be able to provide comments to the Working Group for their consideration. Comments expressed by the public, and in stakeholder meetings, and through mail and e-mail will be reviewed and considered by the Working Group prior to the final development of the draft Ordinance.
- Creation of a Stakeholder Database The Working Group has developed a stakeholder database, which includes all stakeholder contact information (industry, government, working group, etc.), feedback received at stakeholder meetings as well as which stakeholder provided comments, meeting notes, calendar of meetings, and resource files. The database has been a valuable resource to maintain coordination between several departments involved in the Working Group. The database will provide a mechanism to assure stakeholder feedback is documented in an organized and easily accessible location.
- **Announcements of the Public Meetings** Flyers have been created to announce the initial public meetings. The Working Group expects to continue the use of this conventional outreach as well as other mediums for timely meeting announcements to the public.
- Invitation to Participate in Meetings with County Representatives Meeting invitations have been extended to stakeholders via e-mail including the pharmaceutical industry and other stakeholders interested in the ordinance development.

Item 3: Support and Pursue Extended Producer Responsibility Legislation and Take-Back Programs for Sharps and Pharmaceuticals at the State Level, Consistent with the County's Adopted Legislative Agenda and Roadmap to a Sustainable Waste Management Future

The 2015-16 State Legislative Agenda item 2.7.12 directs the County's Sacramento advocates and County Departments to "Support legislation that places greater emphasis on producer/manufacturer responsibility for the environmental impact of their products and the waste that is produced, and shifts end-of-life management and financial responsibilities from local governments to producers, in order to reduce public costs and encourage improvements in product design that promote environmental sustainability." During the current legislative session only one bill related to EPR and sharps or pharmaceuticals was introduced in the Legislature, as described below.

Assembly Bill 1159

During the first year of the 2015-16 State legislative session, Assembly Bill 1159 (AB 1159) was introduced by Assembly Member Richard Gordon. AB 1159 would require a product stewardship organization to submit a product stewardship plan to the Department of Resources Recycling and Recovery (CalRecycle) by July 1, 2017, for covered products, which are defined as home-generated sharps waste and household batteries. The Stewardship Organization would be required to carry-out the plan as a pilot program until January 1, 2024, and to submit annual reports to CalRecycle describing activities of the program and whether performance standards established by CalRecycle are met.

The County expressed its support to its legislative advocates in Sacramento soon after AB 1159 was introduced by Assembly Member Richard Gordon. AB 1159 is a 2-year Bill at the request of the author in order to provide additional time for debate and general discussion on the merits of the Bill, which may be brought back for legislative consideration in early 2016. The County will continue to express its support for AB 1159, so long as it remains consistent with the County's legislative agenda and will evaluate and support other relevant EPR Bills related to pharmaceutical and sharps waste, as they arise.

Next Steps

As directed by the Board in the August 11, 2015, motion, the Interim Chief Executive Officer, the Sustainability Council, and the Working Group are conducting stakeholder meetings to solicit feedback, analyzing similar ordinances and discussing those ordinances with the various jurisdictions in the State, and reviewing best practices of EPR implementation from around the world, prior to drafting the County's EPR Ordinance.

Upon consideration and adoption of the Ordinance by the Board, regulations will be developed including a product stewardship plan for the Take-Back Program. The stewardship plan for the Pharmaceutical Take-Back Program by manufacturers and producers will include, among other things: (1) collection services; (2) handling and disposal procedures; (3) public education and outreach strategies; and (4) tracking reports of disposal amounts, short-term and long-term goals for collection amounts, and educational and promotional outreach to residents.

APPENDIX A



GAIL FARBER, Director

COUNTY OF LOS ANGELES

DEPARTMENT OF PUBLIC WORKS

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July 2, 2015

Gail Farber Laudarhun Director of Public Works

BOARD MOTION OF JUNE 2, 2015, ITEM 78-A MANAGING UNUSED AND EXPIRED MEDICATIONS AND SHARPS WASTE IN THE COUNTY OF LOS ANGELES

On June 2, 2015, the Board approved a motion introduced by Mayor Michael D. Antonovich, as amended, directing the Director of Public Works, in coordination with the Interim Chief Executive Officer; County Counsel; the Sheriff; the Directors of Health Services, Internal Services, Mental Health, and Public Health; and the County Sanitation Districts to:

- 1. Investigate options for reducing improper use and disposal of unused/expired medications, increasing public awareness and education, and improving the current management system for unused/expired medications in the County;
- 2. Partner with the pharmaceutical industry to develop a public awareness campaign to educate residents on the importance of how to properly store and dispose of unused medication and the negative effects to the environment when medication enters the waste stream and waterways;
- 3. Actively support and pursue Extended Producer Responsibility (EPR) legislation and take-back programs for sharps and pharmaceuticals at the State level, consistent with the County's adopted Legislative Agenda and Roadmap to a Sustainable Waste Management Future;
- 4. Investigate the feasibility of adopting an ordinance similar to the pharmaceutical take-back ordinance adopted by the Counties of Alameda, San Mateo, San Francisco, and Santa Clara; and
- 5. Investigate the feasibility of utilizing the County's purchasing power to negotiate producer/pharmacy take-back programs.

Report back within 4 months with findings and recommendations for items 1-3 and report back in 30 days for items 4 and 5.

Each Supervisor July 2, 2015 Page 2

The attached report is in response to items 4 and 5 of the motion. Below is a summary of the findings and conclusion of the report.

Item 4: Pharmaceutical Take-Back Ordinance

The County Departments and Agency listed in the motion formed a Working Group to evaluate the feasibility of adopting an ordinance similar to the pharmaceutical waste take-back ordinances adopted by the Counties of Alameda (July 10, 2012), San Francisco (March 17, 2015), San Mateo (May 19, 2015), and Santa Clara (May 28, 2015).

Utilizing the principle of EPR, an environmental policy introduced in Sweden in 1990, these Counties adopted ordinances that mandate drug manufacturers design and implement a safe take-back and disposal program. Based on this premise and for the additional reasons cited below, the Working Group has determined that a similar ordinance is feasible for the County:

- The United States Drug Enforcement Agency promulgated regulations at, *inter alia*, 21 CFR Parts 1317, *et seq.* in 2014 allowing the collection of controlled substances at collection receptacles, take-back events, and mail-back programs.
- To date, there is no voluntary or mandatory Statewide product stewardship program for unwanted or expired pharmaceuticals or sharps waste in California.
- Publicly financed take-back programs are currently not adequate to manage the amount of unused pharmaceuticals produced in the County.
- ➤ The California Medical Waste Management Act allows local jurisdictions to promulgate more stringent requirements to dispose of medical waste pursuant to Health and Safety Code section 117800.
- In May of this year, the United States Supreme Court declined to review a challenge to Alameda County's Drug Disposal Ordinance. The Court's decision upholds the 9th Circuit Court of Appeals' opinion of September 30, 2014, which found that the ordinance, requiring pharmaceutical manufacturers to fund drug take-back programs in the County, did not interfere with interstate commerce or discriminate against out-of-state manufacturers.

Item 5: Utilization of the County's Purchasing Power to Negotiate a Take-Back Program

The Working Group does not recommend pursuing this strategy. While the County's purchasing power is prominent in many areas based on its sheer volume, most retail pharmaceutical purchases are attributed to the thousands of community and retail pharmacies located within the County. County pharmaceutical purchases make up less than 3 percent of the overall pharmaceutical sales in Los Angeles County.

Each Supervisor July 2, 2015 Page 3

Recommendation

The Working Group recommends the Board adopt an EPR ordinance similar to those adopted by the Counties of Alameda, San Francisco, San Mateo, and Santa Clara requiring manufacturers/producers to develop and finance a product stewardship plan that addresses a take-back program, identifying at a minimum:

- Collection systems and services, including drop-off sites, collection events, and mail-back services;
- Handling and disposal procedures that are safe and in compliance with applicable Federal and State laws;
- Public education and outreach promotion strategies; and
- Tracking reports of disposal amounts, short-term and long-term goals for collection amounts, and education and promotion programs.

Ordinances adopted by San Francisco, San Mateo, and Santa Clara were modeled after Alameda County, but contain other components, such as over-the-counter pharmaceutical waste. As these other ordinances have not been tested legally, there is potential risk of legal challenge associated with including these other components. However, the Working Group has considered these risks and believes that they are outweighed by the benefits of achieving the policy goals.

Next Steps

Upon the Board's direction, the Working Group will prepare a draft EPR ordinance with participation of stakeholders that ensures the safe and convenient take-back and disposal of sharps and pharmaceutical waste by producers and manufacturers. Additionally, the Working Group will report back to the Board by October 2, 2015, regarding items 1-3 of the June 2, 2015, Board order.

If you have any questions regarding this matter, please contact me or your staff may contact Shari Afshari at (626) 458-4008.

CS:ao

h/adhome/ag/EPD/Pharma EPR Cover Memo

Attach

cc: Chief Executive Office (Sachi A. Hamai, Rochelle Goff), County Counsel, Executive Office, Department of Health Services, Internal Services Department, Department of Mental Health, Department of Public Health, Sheriff's Department, Sanitation Districts of Los Angeles County

MANAGING UNUSED AND EXPIRED MEDICATIONS AND SHARPS WASTE IN THE COUNTY OF LOS ANGELES

A report on the feasibility of adopting a pharmaceutical take-back ordinance and utilizing the County's purchasing power to negotiate take-back programs

July 2, 2015

PREPARED BY:

Chief Executive Office
County Counsel
Department of Health Services
Internal Services Department
Department of Mental Health
Department of Public Health
Department of Public Works
Sheriff's Department
Sanitation Districts of Los Angeles County

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INTRODUCTION

MOTION

On June 2, 2015, the Board of Supervisors approved a motion introduced by Mayor Michael D. Antonovich directing the Director of Public Works, in coordination with the Interim Chief Executive Officer; County Counsel; the Sheriff; the Directors of Health Services, Internal Services, Mental Health, and Public Health; and the County Sanitation Districts to:

- 1. Investigate options for reducing improper use and disposal of unused/expired medications, increasing public awareness and education, and improving the current management system for unused/expired medications in the County;
- 2. Partner with the pharmaceutical industry to develop a public awareness campaign to educate residents on the importance of how to properly store and dispose of unused medication and the negative effects to the environment when medication enters the waste stream and waterways;
- Actively support and pursue extended producer responsibility legislation and take-back programs for sharps and pharmaceuticals at the State level, consistent with the County's adopted Legislative Agenda and Roadmap to a Sustainable Waste Management Future;
- 4. Investigate the feasibility of adopting an ordinance similar to the pharmaceutical take-back ordinance adopted by the Counties of Alameda, San Mateo, San Francisco, and Santa Clara; and
- 5. Investigate the feasibility of utilizing the County's purchasing power to negotiate producer/pharmacy take-back programs.

Report back within 4 months with findings and recommendations for items 1-3 and report back in 30 days for items 4 and 5. The County Departments and Agency listed in the motion formed an Extended Producer Responsibility Working Group (EPR Working Group) to prepare this report, which is in response to items 4 and 5 of the motion.

BACKGROUND

Pharmaceuticals play a critical role in treating diseases and saving lives. However, there are times consumers of pharmaceuticals no longer need the supply that is in their possession – for example, their physician has changed their medication therapy, the medication is expired, or a patient in a long-term care facility has died. Current options for managing this excess pharmaceutical supply, or pharmaceutical waste, are limited. Pharmaceutical waste includes unused and/or expired over-the-counter or prescription tablets, oral liquids and injectable products, but also may contain biomedical or biohazardous waste. For this reason, pharmaceutical waste disposal options must provide for the management of biomedical and biohazardous waste as well as disposal of devices commonly used to

puncture the skin (e.g., syringes/needles) that are also used by consumers to inject pharmaceuticals. The U.S. Environmental Protection Agency (USEPA) states that "reducing, minimizing, or eliminating leftover drugs represents a very significant opportunity to improve both ecological and human health while also reducing expenses associated with medical care and waste treatment." In addition, improper management of discarded sharps waste such as needles, syringes, and lancets can pose a health risk to residents, including certain classes of workers and children.²

The safe disposal of pharmaceutical and sharps waste is a public safety and environmental need that calls for safe, convenient, and sustainable disposal options for residents in Los Angeles County.

Health and Safety Issues

According to the National Community Pharmacists Association (NCPA), an estimated 200 million pounds of unused or expired prescription drugs are stored in medicine cabinets across America.³ Given the limited waste disposal options available and the fact that many County residents are unsure of how to safely and properly dispose of pharmaceutical and sharps waste, there is an opportunity for Los Angeles County to take action to provide additional waste disposal options.

Improperly disposed sharps waste poses an additional set of concerns and risks to health professionals, pharmacists, law enforcement professionals, and the waste management industry as these individuals may unexpectedly encounter disposed needles and other related waste. The USEPA estimates that about 8 million people in the United States use more than 3 billion needles, syringes, and lancets, collectively known as "sharps," each year.⁴ Once used, these sharps are termed "home generated" medical waste, and by State law,⁵ are prohibited from disposal in regular trash cans or recycle bins. The volume of home generated sharps waste has been growing in recent years, and many people are unaware of what to do with their used sharps and end up throwing them in the trash despite the law. According to the USEPA "people at the greatest risk of being stuck by used sharps include sanitation and sewage treatment workers, janitors and housekeepers, and children." Much of the home-generated waste is sorted and processed before landfilling, which exposes sanitation workers and others to potentially dangerous conditions. According to the USEPA, all needle-stick injuries are treated as if the needle were infected with a disease. Victims of sharps-related injuries face the cost of post-injury testing, disease prevention measures, and counseling, even if no infection or disease was spread.

¹ Drug Disposal & Stewardship: Ramifications for the Environment and Human Health (USEPA, Sept. 2014)

² Community Options for Safe Needle Disposal (USEPA, Oct. 2004)

³ DisposeMyMeds.org (NCPA, downloaded June 17, 2015)

⁴ Community Options for Safe Needle Disposal (USEPA, Oct. 2004)

⁵ California Health and Safety Code §118286

⁶ Community Options for Safe Needle Disposal (USEPA, Oct. 2004)

Some diseases can take a long time to appear on test results, leading to months of testing and apprehension.⁷

Environmental Issues

The World Health Organization (WHO) recently reported that "a number of studies found trace concentrations of pharmaceuticals in wastewater, various water sources, and some drinking-waters." Pharmaceuticals can enter the environment through multiple pathways, including being poured down the drain, being flushed down toilets, or via trash disposal, which can result in landfill leachate that may enter groundwater. All landfills generate leachate – the product of moisture in the deposited trash and rainfall on the surface of the landfill that collects over time. In landfills operated by the Sanitation Districts of Los Angeles County and most large landfills, the leachate is collected and treated at local wastewater treatment plants. However, municipal wastewater treatment plants in Los Angeles County are not designed to manage or remove all of the complex compounds in pharmaceutical waste, and cannot be cost-effectively retrofitted to do so. The long-term environmental impacts of the presence of pharmaceuticals in groundwater and surface water bodies are unknown; therefore, it is prudent to encourage other methods of disposal.

Financial Issues

The Los Angeles County Sheriff's Department has set up collection and drop-off boxes at 21 stations where residents can safely and anonymously drop off their expired and unused pharmaceutical and sharps waste. In 2013, the Sheriff's program collected about 20,000 pounds of pharmaceutical waste and 26,000 pounds of sharps waste, at a cost of over \$34,000 and \$48,000, respectively, funded through the Sherriff's Department existing budget and personnel. However, this program by itself is simply not adequate to process the volume of pharmaceutical and sharps waste produced in the County.

In addition, the County's Household Hazardous Waste (HHW) Program, managed by Public Works, also collects non-controlled pharmaceutical and sharps waste from residents at weekly HHW collection events and designated collection centers. The \$10 million HHW Program is primarily funded by a Countywide fee collected based on the total amount of solid waste disposed. This funding source is anticipated to substantially decrease as the State proceeds to achieve its policy goal to recycle at least 75% of the waste by 2020, and the County achieves its ambitious waste diversion goals identified in the County's Roadmap to Sustainable Waste Management Future. It is difficult to calculate the exact costs for the collection and management of pharmaceutical and sharps waste from the total HHW Program costs, but they are estimated to be in the range of \$500,000 per year or more. As the County's population continues to increase, demands on these programs will grow, while funding is anticipated to decrease as described above. At the same time, providing for proper management of pharmaceutical and sharps waste for all County residents solely

⁷ Ibid.

⁸ *Information sheet: Pharmaceuticals in drinking-water* (WHO, 2012)

through the HHW Program would require significant additional resources, which is not financially sustainable in the long term.

OPTIONS FOR MANAGING PHARMACEUTICAL AND SHARPS WASTE

Existing options for managing pharmaceutical and sharps waste are described below:

DISPOSAL

Disposal practices that involve placing medications in household trash, pouring them down the drain, or flushing them down the toilet potentially pose a threat to the environment. The U.S. Food and Drug Administration (FDA) recommends that, if take-back options are not available, certain pharmaceutical waste "that may be especially harmful and, in some cases, fatal with just one dose" should be "flushed down the sink or toilet as soon as they are no longer needed." However, the California Department of Resources Recycling and Recovery (CalRecycle) notes "wastewater treatment plants are not designed to remove pharmaceuticals and studies show that exposure to even low levels of drugs has negative effects on fish and other aquatic species, and also may negatively affect human health. Thus, we recommend households do not dispose of waste medication down the drain or down the toilet." 10

In addition, California Law prohibits the placement of sharps waste in trash or recycling bins, and requires that sharps waste be placed in special container to minimize the risk of injury and prevent leakage or expulsion of waste contents during storage and transport.¹¹ Therefore, home disposal of sharps waste is not an option.

There is broad consensus, including among the FDA,¹² USEPA¹³ and the pharmaceutical industry,¹⁴ that take-back programs that promote incineration disposal methods are the preferred choice for proper disposal of expired or unwanted prescription and over-the-counter medication. The USEPA recommends incineration as the preferred method of disposal to address both environmental concerns and concerns regarding improper use of pharmaceuticals.¹⁵ The USEPA notes "studies have shown active pharmaceutical ingredients are present in some groundwater and drinking water, some portion of which is likely due to flushing [down the drain/toilet]. Further, some limited studies have shown active pharmaceutical ingredients present in landfill leachate that is collected in municipal solid waste landfill leachate systems. Incineration of unwanted household pharmaceuticals

⁹ Disposing of Unused Medicines: What You Should Know (FDA, downloaded June 17, 2015)

¹⁰ Household Medication Waste Disposal (CalRecycle website, downloaded June 17, 2015)

¹¹ California Health and Safety Code §§118275-118320

¹² Disposing of Unused Medicines: What You Should Know (FDA website, downloaded June 17, 2015)

¹³ Community Options for Safe Needle Disposal (USEPA, Oct. 2004)

¹⁴ Safe Disposal of Prescription Medication and Environmental Protection (Pharmaceutical Research and Manufacturers of America website, downloaded June 17, 2015)

 $^{^{15}}$ Recommendation on the Disposal of Household Pharmaceuticals Collected by Take-Back Events, Mail-Back, and Other Collection Programs (USEPA Memorandum, Sept. 2012)

will reduce the amount of household pharmaceuticals that are disposed by both flushing and land filling." 16

TAKE-BACK AND MAIL-BACK

Take-back programs are a simple, safe and efficient option to provide for the environmentally safe collection and disposal of pharmaceutical and sharps waste. Through such programs, pharmaceutical and sharps waste are properly contained, incinerated and/or safely disposed. Take-back programs should include a mail-back option, which helps to ensure that the take-back program is accessible to all County residents free of charge, including those who are home bound, live in remote or rural areas, or have a large quantity of pharmaceutical and/or sharps waste that requires disposal. A take-back program with a mail-back option provides for the disposal of pharmaceutical and sharps waste that can be financially, socially, and environmentally sustainable. Three options for implementing a take-back program are discussed below:

Utilizing the County's Purchasing Power for Take-Back

An option considered was the use of the County's pharmaceutical purchasing power to negotiate contracts. However, after review and consideration, the EPR Working Group does not recommend pursuing this strategy. While the County's purchasing power is prominent in many areas based on its sheer volume, most retail pharmaceutical purchases are attributed to the thousands of community and retail pharmacies located within the County. County pharmaceutical purchases make up less than 3% of the overall pharmaceutical sales in Los Angeles County.¹⁷

Publicly Financed Take-Back Program

Today in Los Angeles County, publicly financed take-back programs are the only safe options for residents to dispose of sharps and pharmaceuticals. However, these programs are currently not adequate to manage the amount of unused pharmaceuticals produced in the County. Currently, the County's program relies on a network of pharmaceutical and sharps waste drop-off locations at Sheriff Stations and designated County health centers; however, these limited locations have faced difficulty with safely handling the volume of pharmaceutical and sharps waste, particularly given the types of waste disposed of by consumers and the volume of waste. The County's HHW Program may not provide a convenient location to every resident in a timely manner to manage their sharps or pharmaceutical waste. Expanding these programs sufficiently would require additional resources; however, as discussed above, the Countywide HHW Program is facing anticipated decreases in funding. Given the limited public take-back options due to funding requirements, the County cannot assume the sole responsibility for developing, financing, advertising, and implementing take-back programs. In addition, a recent study by the City

¹⁶ Ibid.

¹⁷ KFF Total Retail Sales for Prescription Drugs Filled at Pharmacies (KFF Website, Downloaded June 25, 2015)

of San Francisco suggests that residents prefer dropping off pharmaceuticals at pharmacies rather than police stations by a wide margin. 18

Establishing a Privately Financed Take-Back Program

In November 2008, the Los Angeles County Board of Supervisors adopted a resolution supporting the principle of Extended Producer Responsibility (EPR). environmental policy approach credited as being officially introduced in Sweden in 1990¹⁹ in which a manufacturer or producer's responsibility for a product is extended to the postconsumer stage of a product's life cycle. Manufacturers would be required, either individually or collectively, to establish a comprehensive take-back program, along with a plan to ensure the program effectively collects the pharmaceutical products at the end of their useful life. In addition to assuming a share of the costs, EPR can lead to better results overall since manufacturers know their product and industry better and can design and operate collection and disposal programs which are more efficient and effective than those implemented by local governments. A take-back program financed by the pharmaceutical industry would share the responsibility for managing unused/expired pharmaceuticals and sharps and relieve the current burden on publicly funded efforts. This program would include handling the shipping costs incurred through the use of a mail-back option for consumers. According to the Product Stewardship Institute, the EPR approach has been successful in managing pharmaceutical and sharps waste for years throughout some European countries, Mexico, and Canada.²⁰

The State Board of Pharmacy is in the process of establishing regulations for pharmaceutical take-back within pharmacies. As the Drug Enforcement Agency regulations also allow take-back within hospitals and long-term care facilities when overseen by a pharmacy, the regulations will include these additional access areas as well.

Generally, EPR programs are more effective when adopted uniformly for a geographically large area, allowing for improved economies of scale for outreach and collection costs while minimizing confusion that may arise over the boundaries of local programs. However, previous attempts to pass Statewide EPR legislation for pharmaceuticals and sharps in California have not been successful. On July 10, 2012, Alameda County was the first County in the nation to adopt an EPR ordinance for pharmaceutical waste at the local level. Alameda County's Safe Drug Disposal ordinance was challenged by the pharmaceutical industry in District Court, and when it was upheld, appealed to the Ninth Circuit Court of Appeals which also upheld the ordinance. On May 26, 2015, the United States Supreme Court decided that it would not review the case, leaving the Ninth Circuit Court decision in

¹⁸ San Francisco's Safe Medicine Disposal Pilot Program Update (San Francisco Public Utilities Commission, Jan. 2013)

¹⁹ The Concepts of Extended Producer Responsibility and Product Stewardship (Institute For Local Self-Reliance Website, Downloaded June 25, 2015)

 $^{^{20}}$ Myths vs. Reality: Extended Producer Responsibility for Pharmaceuticals (Product Stewardship Institute, factsheet downloaded June 17, 2015)

place. Also, this year three additional Counties in California–Santa Clara, San Francisco, and San Mateo–have adopted similar ordinances.

A SUSTAINABLE SOLUTION

Adopting an EPR ordinance to establish a privately financed take-back program for pharmaceutical and sharps waste is a sustainable and effective approach, since it requires the manufacturers, as producers of pharmaceutical products and sharps, to incorporate into the price of their products the cost of managing the products at the end of their useful life. Manufacturers can partner with pharmacies to establish take-back locations, which would be more convenient to residents, and it is anticipated that financing these programs will have minimal impact on the retail costs of pharmaceuticals or sharps.^{21,22}

On October 21, 2014, the Board of Supervisors adopted the Roadmap to a Sustainable Waste Management Future (Roadmap). The Roadmap identifies strategies and initiatives to reduce waste and divert material from landfills. One of the initiatives identified is to advocate for EPR, including exploring the feasibility of establishing a County EPR ordinance for materials such as pharmaceutical and sharps waste.

Additionally, supporting shared responsibility with manufacturers for the impacts and management costs of their products at the end of life is consistent with the County's Legislative Agenda, which states that the County will "support legislation that places greater emphasis on producer/manufacturer responsibility for the environmental impact of their products and the waste that is produced, and shifts end-of-life management and financial responsibilities from local governments to producers, in order to reduce public costs and encourage improvements in product design that promote environmental sustainability." This policy was established following the Board of Supervisors adoption on November 5, 2008, of a resolution "supporting Extended Producer Responsibility and directing the County's Legislative Advocates in Sacramento to actively pursue legislation and Statewide policies that shift end-of-life product management costs from local government to the manufacturers and incentivize the redesign of products that have impacts on public health and the environment."

The overall efforts are in line with the June 2014 County Strategic Plan Goal No. 2, Strategic Initiative 5, Environmentally Sustainable Practices which identifies a specific focus area promoting net-zero waste in order to "optimally manage and reduce solid waste by diverting from waste stream and maximizing recycling opportunities."

²¹ Ibid.

²² Economic Impacts of the B.C. Recycling Regulation (British Columbia, CN Ministry of Environment, August 2008)

²³ 2015-16 State Legislative Agenda, Section 2.7.12 (Los Angeles County, Dec. 2014)

RECOMMENDATION

The Board directed that the Department of Public Works in coordination with the Chief Executive Office, County Counsel, the Sheriff, Health Services, Internal Services, Mental Health, Public Health, and the County Sanitation Districts address the issue of take-back programs for pharmaceutical products. This EPR Working Group recommends the Board adopt a pharmaceutical and sharps waste EPR ordinance in which pharmaceutical manufacturers and producers would develop and fund take-back programs providing collection services that are reasonably convenient and adequately meet the needs of the population being served.

PHARMACEUTICAL AND SHARPS WASTE EPR ORDINANCE

The Working Group recommends that this ordinance require manufacturers/producers of prescription and nonprescription drugs (including controlled and non-controlled substances) as well as sharps to develop product stewardship take-back program(s) to collect and dispose of unused/unwanted pharmaceutical and sharps waste from consumers. Ordinances adopted by San Francisco, San Mateo, and Santa Clara were modeled after Alameda County's ordinance, but contain other components, such as overthe-counter pharmaceutical waste, as well as requiring other best practices. As these other ordinances have not been tested legally, there is potential risk of legal challenge associated with including these other components. However, the EPR Working Group has considered these risks and believe that they are outweighed by the benefits of achieving the policy goals.

All pharmaceutical manufacturers/producers would be subject to the same requirement to design and implement a take-back program, and they would be able to choose whether to meet these requirements individually or by joining with others. Manufacturers/producers would have the flexibility to design the take-back program to meet performance goals established by the County. The County would be responsible for oversight of the program(s), for ensuring that the program(s) are transparent and readily accessible to the public, and that a thorough outreach program is implemented.

Participation by retail pharmacies, hospitals, and long-term care facilities would be voluntary, and interested pharmacies would work directly with the pharmaceutical producers to join the program. Any pharmacies, hospitals, or nursing homes that choose to participate would provide collection bins for pharmaceutical and sharps waste, contribute floor space and staff time to manage the collected materials and answer consumers' questions. The EPR Working Group recommends that the ordinance authorize pharmaceutical manufacturers/producers to provide financial incentive to participating pharmacies. The EPR Working Group also recommends the ordinance require any retail pharmacy not participating as a collection point, at minimum to advertise options available for proper disposal, including the locations of participating pharmacies and how to make use of mail-back programs.

NEXT STEPS

DRAFT ORDINANCE

Upon the Board's direction, the EPR Working Group will prepare a draft pharmaceutical waste and sharps waste EPR ordinance with the participation of stakeholders. The ordinance would be drafted as a Countywide ordinance, however it is anticipated that each city wishing to participate would need to take additional action, as the ordinance may only be enforceable in a city's jurisdiction after the city takes action to adopt the County ordinance by reference.

Additionally, the EPR Working Group will report back to the Board by October 2, 2015, with findings and recommendations related to items 1-3 of the Board motion as stated on page 4 of this report.

CONDUCT OUTREACH

If the Board directs the EPR Working Group to move forward with drafting an ordinance, the EPR Working Group will initiate stakeholder engagement to the pharmaceutical industry and other stakeholders to solicit their feedback. The EPR Working Group would work together to develop a refined list of stakeholders and host public information meetings. The meetings would be organized to provide industry and other stakeholders with an opportunity to share and discuss their comments and concerns regarding the concept of a pharmaceutical and sharps waste EPR ordinance.

The following target audiences and types of stakeholders have been identified for outreach. A more specific and extensive list will be developed based on the experiences of other Counties that have developed similar ordinances.

Stakeholder Engagement Objectives:

- Communicate the need to provide safe, convenient, and sustainably financed take-back options for consumers to properly dispose of pharmaceutical and sharps waste
- Obtain feedback from industry and other stakeholders
- Generate awareness about the EPR program

Target Audiences:

- General Public
- Drug Abuse Advocacy Groups
- Waste Management Companies
- Environmental Advocacy Groups
- Senior Citizen Advocacy Groups
- Pharmacy Industry Representatives and Associations
- Pharmaceutical Manufacturers and Associations
- Cities within Los Angeles County
- Veterinarian Organizations
- Health Care Provider Organizations

VII. MISCELLANEOUS

- **78.** Additions to the agenda which were posted more than 72 hours in advance of the meeting, as indicated on the supplemental agenda. (12-9995)
- 78-A. Recommendation as submitted by Supervisor Antonovich: Instruct the Director of Public Works, in coordination with the Interim Chief Executive Officer, County Counsel, Sheriff, the Directors of Health Services, Internal Services, Mental Health and Public Health, and the County Sanitation Districts to report back within 4 months with the findings and recommendations on the following:

Investigate options for reducing improper use and disposal of unused/expired medications, increasing public awareness and education and improving the current management system for unused/expired medications in the County;

Partner with the pharmaceutical industry to develop a public awareness campaign to educate residents on the importance of how to properly store and dispose of unused medication and the negative effects to the environment when medication enters the waste stream and waterways;

Actively support and pursue extended producer responsibility legislation and take-back programs for sharps and pharmaceuticals at the State level, consistent with the County's adopted Legislative Agenda and Roadmap to a Sustainable Waste Management Future;

Investigate the feasibility of adopting an ordinance similar to the pharmaceutical take-back ordinance adopted by the Counties of Alameda, San Mateo, San Francisco and Santa; and

Investigate the feasibility of utilizing the County's purchasing power to negotiate producer/pharmacy take-back.

Supervisor Antonovich revised Recommendation Nos. 4 and 5 to request a report back to the Board in 30 days.

On motion of Supervisor Knabe, seconded by Supervisor Antonovich, this item was approved as amended. (15-2619)

Ayes:

5 -

Supervisor Solis, Supervisor Ridley-Thomas, Supervisor Kuehl, Supervisor Knabe and

Supervisor Antonovich

Attachments:

Motion by Supervisor Antonovich

Report Video Audio

AGN.	NO.	
	-	

MOTION BY MAYOR MICHAEL D. ANTONOVICH

JUNE 2, 2015

Managing unused/expired medications is a growing concern facing the County of Los Angeles. According to the National Community Pharmacists Association, an estimated 200 million pounds of unused or expired prescription drugs are stored in American medicine cabinets. They often end up in the wrong hands where inappropriate use can lead to addiction, abuse, serious injury, and even death. According to a report released by the Department of Public Health, in 2013 there were more than 500 deaths, 3,000 hospitalizations and 5,000 emergency visits associated with prescription and over the counter drug overdose in Los Angeles County.

New studies are also demonstrating that pharmaceuticals have an impact on our environment. The World Health Organization recently reported that "a number of studies found trace concentrations of pharmaceuticals in wastewater, various water sources and some drinking-waters." Municipal wastewater treatment plants are not designed to remove the complex compounds in drugs that end up in the sewer system.

Pharmaceuticals delivered via needles pose an additional set of concerns, posing a risk to health professionals as well as public and private employees in law enforcement and waste management that interact with disposed needles and related sharps waste.

These are serious problems impacting the well-being of our communities. In response, the Sheriff's Department has set up collection and drop-off boxes at 21 stations where residents can safely, and anonymously, drop off their expired medications and sharps. The County's Household Hazardous Waste program, managed by Public Works, also collects non-controlled pharmaceuticals and sharps from residents. Unfortunately, the volume of pharmaceuticals is too great for local programs such as this to fully address the problem. We need to do more to increase public awareness of the potential impacts of improper storage and disposal of unused medication and to make it safe and convenient for residents to dispose of unused/expired medications and increase participation.

-MORE-

	MOTION
SOLIS	
RIDLEY-THOMAS	
KUEHL	
KNABE	
ANTONOVICH	

I, THEREFORE, MOVE that the Board of Supervisors:

Direct the Director of Public Works, in coordination with the Chief Executive Office; County Counsel; the Sheriff's Department; the Departments of Health Services, Internal Services, Mental Health and Public Health; and the County Sanitation Districts to:

- 1. Investigate options for reducing improper use and disposal of unused/expired medications, increasing public awareness and education, and improving the current management system for unused/expired medications in the County;
- Partner with the pharmaceutical industry to develop a public awareness campaign to educate residents on the importance of how to properly store and dispose of unused medication and the negative effects to the environment when medication enters the waste stream and waterways;
- Actively support and pursue extended producer responsibility legislation and take-back programs for sharps and pharmaceuticals at the State level, consistent with the County's adopted Legislative Agenda and Roadmap to a Sustainable Waste Management Future;
- 4. Investigate the feasibility of adopting an Ordinance similar to the pharmaceutical take-back ordinance adopted by the Counties of Alameda, San Mateo, San Francisco and Santa Clara;
- 5. Investigate the feasibility of utilizing the County's purchasing power to negotiate producer/pharmacy take-back programs; and
- 6. Report back within 4 months with findings and recommendations.

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MDA:evo pharmaceuticalsdisposal060215